

WHAT IS CLAIMED IS:

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1. A combined radiation and radiosensitizer delivery catheter for inhibiting hyperplasia, comprising:  
a catheter body having a proximal end and a distal end;  
an ionizing radiation source coupleable to the catheter body for applying a radiation dose to a body lumen; and  
means coupleable to the catheter body or the radiation source for releasing a radiosensitizer to the body lumen.
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2. A delivery catheter as in claim 1, wherein the ionizing radiation source is an x-ray tube.
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3. A delivery catheter as in claim 1, wherein the ionizing radiation source is a radioisotope.
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4. A delivery catheter as in claim 1, wherein the ionizing radiation source is a receptacle in the catheter body for receiving radioisotopic materials.
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5. A delivery catheter as in claim 1, wherein the means comprises a source of at least one radiosensitizer selected from the group consisting of taxol, misonidazole, metronidazole, etanidazole, 5-fluorouracil, texaphyrin, C225, and cyclooxygenase-2 inhibitor.
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6. A delivery catheter as in claim 1, wherein the means comprises a source of taxol incorporated in a solution with polyoxyethylated castor oil and dehydrated alcohol.
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7. A delivery catheter as in claim 1, wherein the radiosensitizer is attached or encapsulated in a lipid or surfactant carrier.
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8. A delivery catheter as in claim 1, wherein the means for releasing the radiosensitizer comprises a microporous balloon on the catheter body.
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9. A delivery catheter as in claim 8, wherein the microporous balloon contains the radiosensitizer and the radiosensitizer is released from the microporous balloon by elution from pores.

1 10. A delivery catheter as in claim 9, wherein the microporous balloon is  
2 inflatable with the radiosensitizer.

1 11. A delivery catheter as in claim 1, wherein the means for releasing the  
2 radiosensitizer comprises a matrix formed over at least a portion of a balloon on the catheter  
3 body, wherein the radiosensitizer is in or beneath the matrix.

1 12. A delivery catheter as in claim 11, wherein the matrix comprises a rate  
2 controlling material, wherein the rate controlling material controls the rate at which the  
3 radiosensitizer is released from or through the matrix.

1 13. A delivery catheter as in claim 12, wherein the radiosensitizer is  
2 released from the matrix by diffusion through the matrix.

1 14. A delivery catheter as in claim 12, wherein the radiosensitizer is  
2 released from the matrix by degradation of the matrix.

1 15. A delivery catheter as in claim 12, wherein the rate controlling material  
2 is porous and the radiosensitizer is released from the material by elution from pores.

1 16. A delivery catheter as in claim 11, wherein the radiosensitizer is  
2 disposed on the balloon.

1 17. A delivery catheter as in claim 8 or 11, wherein the ionizing radiation  
2 source is positionable within the balloon.

1 18. A delivery catheter as in claim 1, wherein the ionizing radiation source  
2 is a radioisotopic balloon and the means for releasing the radiosensitizer comprises a matrix  
3 formed over at least a portion of the radioisotopic balloon, wherein the radiosensitizer is in or  
4 beneath the matrix.

54 19. A delivery catheter as in claim 8, 11, or 18, further comprising  
perfusion threading on an outer surface of the balloon.

1 20. A delivery catheter as in claim 19, wherein the threading has a spiral,  
2 helical, or angled pattern.

21. A delivery catheter as in claim 8, 11, or 18, wherein the catheter body has a perfusion lumen.

22. A combined radiation and radiosensitizer delivery catheter for inhibiting hyperplasia, comprising:  
a catheter body having a proximal end, a distal end, and an infusion lumen for releasing a radiosensitizer;  
a pair of axially spaced apart balloons on the catheter body; and  
an ionizing radiation source coupleable to the catheter body for applying a radiation dose between the axially spaced apart balloons.

23. A delivery catheter as in claim 22, further comprising a source for releasing at least one radiosensitizer selected from the group consisting of taxol, misonidazole, metronidazole, etanidazole, 5-fluorouracil, texaphyrin, C225, and cyclooxygenase-2 inhibitor.

24. A method for inhibiting hyperplasia in a body lumen, said method comprising:  
releasing a radiosensitizer at a target region within the body lumen; and  
directing ionizing radiation at the target region, wherein the radiosensitizer and radiation combine to inhibit hyperplasia.

25. A method as in claim 24, further comprising inflating a balloon at the target region, where the radiosensitizer is released from the balloon.

26. A method as in claim 25, wherein the balloon is inflated with the radiosensitizer and the radiosensitizer is released from an interior of the balloon through pores.

27. A method as in claim 25, wherein the radiosensitizer is released from a surface of the balloon.

28. A method as in claim 27, wherein the radiosensitizer is released through a rate controlling matrix.

1 29. A method as in claim 24, further comprising isolating the target region,  
2 wherein the radiosensitizer is released into the isolated region.

1 30. A method as in claim 29, wherein isolating comprises inflating a pair  
2 of axially spaced apart balloons.

1 31. A method as in claim 29, wherein isolating comprises expanding a pair  
2 of axially spaced apart mechanical barriers.

1 32. A method as in claim 25, wherein the directing comprises positioning  
2 an ionizing radiation source within the balloon.

1 33. A method as in claim 29, wherein the directing comprises positioning  
2 an ionizing radiation source within the isolated target region.

1 34. A method as in claim 32 or 33, wherein the ionizing radiation source is  
2 an x-ray tube and positioning comprises energizing the x-ray tube and translating the x-ray  
3 tube to traverse the target region.

1 35. A method as in claim 32 or 33, wherein the ionizing radiation source is  
2 a radioisotope.

1 36. A method as in claim 32 or 33, wherein the ionizing radiation source is  
2 a receptacle in the catheter body and positioning comprises introducing a radioisotope into  
3 the receptacle.

1 37. A method as in claim 24, wherein the body lumen is a blood vessel and  
2 the target region is a region at risk of hyperplasia.

1 38. A method as in claim 24, wherein the directing comprises applying a  
2 total radiation dose in a range from about 4 Gy to 24 Gy.

1 39. A method as in claim 24, wherein the releasing a radiosensitizer and  
2 directing an ionizing radiation dose are carried out simultaneously.

1 40. A method as in claim 24, wherein the releasing a radiosensitizer and  
2 directing an ionizing radiation dose are carried out sequentially.

1 41. A kit comprising:  
2 a catheter capable of applying a radiation dose and releasing a radiosensitizer  
3 in a body lumen; and  
4 instructions to use the catheter according to any one of claims 24-40.

1 42. A kit as in claim 41, further comprising a source of radiosensitizer.